

K050069

JAN 31 2005

Attachment 12
510(k) Summary for the
Cutera Flashlamp Tabletop Aesthetic Product

I. General Information

Submitter: Cutera, Inc.
3240 Bayshore Boulevard
Brisbane, CA 94005

Contact Person: Kathy Maynor

Summary Preparation Date: November 19, 2004

II. Names

Device Names: Cutera Flashlamp Tabletop Aesthetic Product

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories) 878.4810 - GEX

III. Predicate Devices

- Cutera CoolGlide Aesthetic Lasers With Optional Pulsed Light Hand Piece (K023954)
- Cutera Titan Tabletop Product (K042165)

IV. Product Description

The Cutera Flashlamp Tabletop Aesthetic Product consists of a modified console designed to drive the pulsed light hand pieces, which are all existing, FDA cleared devices. The hand pieces are pulsed light devices with a variable emission of 500-1300nm. The delivered wavelength is filtered to various desired wavelength bands within the 500-1300nm range via coated glass filters to eliminate the extraneous wavelengths.

The Cutera Flashlamp Tabletop Aesthetic Product is comprised of five main components:

- a system console (including software and control electronics);
- a control and display panel;

K050069

Premarket Notification 510(k) Submission:
Cutera Flashlamp Tabletop Aesthetic Product

- a detachable hand piece with integrated skin cooling;
- a foot-operated exposure switch (footswitch); and
- a remote interlock connector (disables emission when treatment room door is opened).

The proximal end of the umbilical cable is semi-permanently attached to the system console and the distal end is permanently attached to the body of the delivery hand piece. This hand piece is removable by either the user or an authorized field service engineer for replacement at the proximal end.

V. Indications for Use

The Cutera Flashlamp Tabletop Aesthetic Product is indicated for the treatment of benign pigmented lesions.

VI. Rationale for Substantial Equivalence

The Cutera Flashlamp Tabletop Aesthetic Product shares the same general indications for use, and therefore is substantially equivalent to the currently cleared pulsed light hand piece (K023954) and the currently cleared tabletop console (K042165). No clinical data is required.

VII. Safety and Effectiveness Information

The indication for use is exactly the same as the previously cleared pulsed light hand piece (K023954).

Technologically, the Cutera Flashlamp Tabletop Product is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the Cutera Flashlamp Tabletop Product are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The Cutera Flashlamp Tabletop Aesthetic Product was found to be substantially equivalent to the currently cleared Cutera pulsed light hand piece (K023954) and Cutera tabletop console (K042165). The Cutera Flashlamp Tabletop Aesthetic Product shares similar indications for use, design features, and similar functional features as, and thus is substantially equivalent to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2005

Cutera, Inc.
c/o Mr. Morten Simon Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K050069

Trade/Device Name: Cutera Flashlamp Tabletop Aesthetic Product

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: January 11, 2005

Received: January 12, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

for 

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Premarket Notification 510(k) Submission:
Cutera Flashlamp Tabletop Aesthetic Product

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K050069

Device Name: **Cutera Flashlamp Tabletop Aesthetic Product**

Indications For Use:

The Cutera Flashlamp Tabletop Aesthetic Product is intended for the treatment of benign pigmented lesions.

Prescription Use ✓
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050069